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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/726,792	11/29/2000	Jon A. Wolff	10.03	5687

7590 08/27/2003
Mark K. Johnson
PO Box 510644
New Berlin, WI 53151-0644

EXAMINER

NGUYEN, DAVE TRONG

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 08/27/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/726,792

Applicant(s)

WOLFF ET AL.

Examiner

Dave T. Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Claims 1-20, to which the following grounds are applicable, are pending.

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 and 119 (e) as follows:

The second application (which is called a continuation in-part application) must be an application for a patent for an invention which is also disclosed in the first application (the parent or provisional application); the disclosure of the invention in the parent application and in the continuation in-part application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *In re Ahlbrecht*, 168 USPQ 293 (CCPA 1971). Both parent non-provisional application 09/234,606 and provisional application 60/167,836 do not have sufficient written support for a generic claim such as claim 1 that embraces the invention of employing a cyclodextrin as one of the main components of a DNA delivery complex to deliver a polynucleotide to a target cell. Thus, the effective filing date of this as-filed application is November 29, 2000

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Hung (WO 97/16169).

The claims encompass a process for delivery of nucleic acid molecules to a cell, which process comprises employing a complex comprising a cyclodextrin associated with an amphiphilic molecule such as a polycationic or polymeric molecule, *e.g.*, polylysine and/or liposomes. Hung teaches a gene delivery method for delivering a gene of interest to the pericardial space of a mammal for expression (abstract), wherein the method comprises the use of a DNA delivery complex, which comprises a polycationic molecule/polymer conjugates, polyanionic molecules, polymer conjugates, lipids, or liposomal/polycationic conjugate (page 36, first par., page 37, fourth and fifth pars., page 40, lines 19-32, page 41, lines 6-11, pages 41-42), wherein the liposomal carrier can be a cyclodextrin liposome (page 58, claim 4).

Absent evidence to the contrary, the delivery process cited in Hung has all of the properties cited in the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject

matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of Sankaran (WO 96/08235), Kim (US 5,759,573) or Kosak (US 6,048,736), taken with any of Niven (US 6,022,737), Ye (WO 99/12523) or Hung (WO 97/16169).

The main thrust of the as-filed invention is the concept of utilizing a cyclodextrin in any known amphiphilic delivery complex so as to enhance the delivery of a gene of interest to a mammal.

Sankaran, Kim, and Kosak are exemplified prior art that teaches it is well established in the prior art to employ cyclodextrin liposomes or cyclodextrin polymers as carrier complexes to enhance the delivery of biologically active molecules including macromolecules to a target cell in a mammal (Sankaran, page 5, lines 10-20, page 13, first full par., page 29, claim 23; Kim, abstract, entire disclosure; Kosak, abstract, entire

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disclosure).

While Sankaran, Kim, or Kosak does not teach that the biologically active molecule or drug can be a gene or polynucleotide, it is also well known in the prior art that cyclodextrin and/or liposomal or polymeric carriers have been employed have been used as carrier complexes to enhance the delivery of a DNA drug to a cell of interest in a mammal, see Niven, claim 8; Ye, abstract, page 10 bridging page 11, page 19 bridging page 20, page 44, claim 15; Hung, (page 36, first par., page 37, fourth and fifth pars., page 40, lines 19-32, page 41, lines 6-11, pages 41-42, and 58).

Thus, it would have been obvious for one of ordinary skill in the art to employ any known cyclodextrin containing amphiphilic complex as carriers to enhance the delivery of a DNA drug or polynucleotide to a cell of interest in a mammal. One of ordinary skill in the art would have been motivated to do so because the prior art exemplified by Niven, Ye, and Hung teaches that it is well known in the prior art that cyclodextrin and/or liposomal or polymeric carriers have been employed have been used as carrier complexes to enhance the delivery of a DNA drug to a cell of interest in a mammal.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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In claim 16, the term "amphiphile binding agent" lacks an antecedent basis, since its base claim does not have any reference with respect to an amphiphile binding agent.

Clarification is requested.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is **(703) 305-2024**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Deborah Reynolds*, may be reached at **(703) 305-4051**.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is **(703) 305-7401**.

Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is **(703) 308-0196**.

Dave Trong Nguyen
Primary Examiner
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DAVE T. NGUYEN
PRIMARY EXAMINER